In the United States Court of Federal Claims

No. 16-498V
(Filed: July 16, 2019)
(Re-issued for Publication: February 19, 2020) [1]

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HEATHER WRIGHT, as the legal representative of her minor son, B.W.,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

National Childhood Vaccine Injury Act; Motion for review; Severity requirement; Residual effect; MMR vaccine; Immune thrombocytopenic purpura ("ITP").

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Leah V. Durant, Washington, DC for petitioner.

Traci R. Patton, Senior Trial Attorney in the Torts Branch of the Civil Division, Department of Justice, Washington, DC, with whom are, *Joseph H. Hunt*, Assistant Attorney General, *C. Salvatore D'Alessio*, Acting Director, *Catharine Reeves*, Deputy Director, and *Heather L. Pearlman*, Assistant Director, for respondent.

OPINION

BRUGGINK, *Judge*.

This case was brought by petitioner, Heather Wright, on behalf of her minor son, B.W., under the National Childhood Vaccine Injury Act

[1] Pursuant to Vaccine Rule 18(b), this opinion was initially filed under seal to afford the parties14 days to propose redactions. The parties did not propose any redactions. Accordingly, this opinion is reissued in its original form for publication.

("Vaccine Act"). The petition alleges that B.W. suffered from immune thrombocytopenic purpura ("ITP") after receiving his measles-mumps-rubella ("MMR") vaccine on March 28, 2014, and is entitled to compensation because the management of the condition through repeated platelet tests satisfies the statute's six-month residual effect requirement. Respondent moved to dismiss for failure to meet the severity requirement. The Special Master agreed with respondent after further briefing and a hearing. The case is now before this court on a motion for review of that decision. The motion is fully briefed, and oral argument was held on July 11, 2019. Because we find the Vaccine Act's severity requirement met in these circumstances, we grant the motion for review and reverse the Special Master's decision.

The petitioner bears the burden of proving by a preponderance of the evidence that it is entitled to compensation under the Vaccine Act. In a Table claim, as is presented here, causation is presumed if the resulting injury, disability, illness, or condition corresponds with the vaccine listed and occurs within the designated time period. *See* 42 U.S.C.S § 300a-14 (2012); 42 C.F.R. § 100.3(a) (2017); *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013). Still, petitioner must prove that the individual experiencing the vaccine-related injury: (1) "suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine," (2) died, or (3) was hospitalized or underwent surgery in response to the vaccine-related illness, disability, injury, or condition. 42 U.S.C.S. § 300aa-11(c)(1)(D).

BACKGROUND

I. Factual History

B.W. was born on March 21, 2012. At his two-year well-child visit on March 28, 2014, he was relatively healthy, although he was behind on vaccinations. He was thus administered MMR, DTap, ActHib, pneumococcal, Hepatitis A, and Varicella vaccines at that visit.

On April 15, 2014, B.W.'s father and paternal grandmother brought him to the Emergency Room at Ty Cobb Regional Medical Center in Lavonia, Georgia after finding bruises on his forehead, abdomen, arms, and legs. X-rays and blood tests were performed. The x-rays were normal but the blood tests showed a low platelet count. His platelet count was 43,000, far below the normal range of 150,000 to 400,000. He was diagnosed with

ITP and discharged that day with a recommendation to see his primary care provider within a week in order to be referred to a hematologist.[2]

Because Ms. Wright did not have many details regarding B.W.'s visit to Ty Cobb the previous day, she was concerned about his ITP diagnosis and brought BW to Children's Healthcare of Atlanta ("CHOA") the following day, April 16, 2014. Another Complete Blood Count ("CBC") was performed, and B.W.'s platelet count was again found to be low at 68,000. The treating physician at CHOA discharged B.W. that day with a diagnosis of "'thrombocytopenia likely secondary to acute ITP.'" *Wright v. Sec'y of Health & Human Servs.*, No. 16-498V, 2019 WL 1061472 at 3 (Fed. Cl. Spec. Mstr. Jan. 18, 2019) (hereinafter "Decision") (quoting Pet'r's Ex. 4 at 91). She also recommended following up with a hematology clinic and suggested finding one closer to home because petitioner lived three hours from CHOA.

Over the next few weeks, B.W.'s platelet count was checked every three to four days by pediatricians at The Longstreet Clinic in Gainesville, Georgia. The counts were as follows: 180,000 on April 21, 181,000 on April 25, 80,000 on April 29, 68,000 on May 2, and 111,000 on May 7. On April 29, 2014, Dr. Garrick Bailey, M.D. referred B.W. to the Hematology/Oncology Department of CHOA. On May 13, 2014, B.W. saw hematologists Benjamin Watkins, M.D. and Michael Briones, D.O., at which point his platelet count was 80,000.[3] Drs. Watkins and Briones reviewed the previous platelet counts and concluded that B.W. had ITP as a result of his MMR vaccine. They recommended follow-up visits "'every 1-2 months until resolution'" since his ITP was not viewed as severe. *Id.* (quoting Pet'r's Ex. 2 at 127).

A follow-up visit was scheduled for June 10, 2014, but was canceled by petitioner due to a stomach bug and never rescheduled. However, on July

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[2] Thrombocytopenia purpura is defined in the Vaccine Act's regulations "by the presence of clinical manifestations, such as petechiae, significant bruising, or spontaneous bleeding, and by a serum platelet count less than 50,000/mm^3 with normal red and white blood cell indices." 42 C.F.R. § 100.3(c)(7).

[3] The International Working Group on ITP uses a platelet count of less than or equal to 100,000/mm^3 to diagnose ITP. Resp't's Ex. B at 2. This is higher than the 50,000/ mm^3 used in the statute. *See* 42 C.F.R. § 100.3(c)(7).

8, 2014, Dr. Bailey performed another platelet count at petitioner's request and concluded that B.W.'s ITP had "resolved." *Id.* (quoting Pet'r's Ex. 2 at 144).

Given B.W.'s history of ITP, the pediatricians who saw him over the next two years continued to order platelet testing in response to his continued presentation with bruising. On September 14, 2014, B.W. was seen for bruising and headaches. His platelet count was 312,000. On January 26, 2015, B.W.'s platelets were counted when he was seen for bruising on his shins and abdomen; the count at that visit was 381,000. On April 13, 2016, platelet testing was ordered after B.W. was brought in for bruising on his back and extremities, as well as petechiae on his mid and lower back.[4] Pet'r's Ex. 9 at 41. B.W.'s platelet count was 289,000. Lastly, on September 14, 2016, B.W. was seen again for bruising and the platelet test showed a platelet count of 318,000.

Between these visits, B.W. was seen several times for bruising, or bruising was indicated on his medical record if he was seen for something else. Those dates include: October 9, 2014 (experienced bruising after falling from a cart), December 5, 2014 (bruising), April 16, 2015 (bruises noted at three-year well-child visit), June 28, 2015 (finger contusion due to car door), and March 2016 (bruises on face after dog bite).[5]

II. Procedural History

On April 21, 2016 Heather Wright filed a petition for compensation on behalf of her minor son under the National Childhood Vaccine Injury Act, 42 U.S.C.S. §§ 300aa-1 to-34 (2012). Petitioner alleged that her son had developed ITP as a result of receiving the MMR vaccine on March 28, 2014. Originally, this case was assigned to the Special Processing Unit because it looked to be a Table claim that was likely to settle. *See* 42 C.F.R. § 100.3(a).

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[4] Petechiae are "'small hemorrhages in the skin.'" *Crabbe v. Sec'y of Health & Human Servs.*, No. 10-762V, 2011 WL 4436742, at *7-8, n.9 (Fed. Cl. Spec. Mstr. Aug. 26, 2011) (quoting Kathleen D. Pagana & Timothy J. Pagana, Mosby's Manual of Diagnostic and Laboratory Tests (4th ed. 2010) at 416).

[5] B.W. was also seen on May 6, 2016, for a nosebleed. Nosebleeds are also a common symptom of ITP. *See Guido v. Sec'y of Health & Human Servs.*, No. 16-435V, WL 4277579, at *7 (Fed. Cl. Spec. Mstr. Aug. 25, 2017).

Respondent, however, filed a combined Vaccine Rule 4(c) Report and a Motion to Dismiss on September 21, 2016, at which point the case was reassigned to Special Master Corcoran. In it, respondent argued that petitioner could not meet the severity requirement for compensation under the Vaccine Act because B.W.'s ITP resolved in less than six months after he received the vaccine. The motion was fully briefed and an evidentiary hearing was held on September 21, 2017.

At the hearing, both parties provided expert testimony. Dr. Catherine Shaer testified for petitioner, and Dr. Joan Gill testified for respondent. Dr. Shaer testified that the continued platelet testing that B.W. underwent when he was seen for bruising, even after Dr. Bailey concluded that B.W.'s condition had resolved, constituted "management of his condition." Hr'g Tr. 22. She explained that, when a child with a recent history of ITP is presented to a medical professional because he exhibits bruising, it is appropriate for platelet counts to be tested. Even though bruises are not in and of themselves diagnostic of ITP, they are "one of the manifestations of a low platelet count that you can actually visually see." Hr'g Tr. 19 (Dr. Shaer).

Dr. Gill, on the other hand, focused on Dr. Bailey's July 8, 2014 declaration that B.W.'s ITP had resolved. She explained the differences between acute and chronic ITP and opined that, though the subsequent testing that B.W. underwent was related to his history of ITP, the platelet counts show that his ITP in fact never returned. Dr. Gill noted, like Dr. Shaer, that, although bruising is symptomatic of ITP, it is not diagnostic unless it is accompanied by a low platelet count.

After a thorough analysis of the facts, Special Master Corcoran found Dr. Gill persuasive and concluded that petitioner had not met the Vaccine Act's severity requirement. He held that subsequent monitoring of an earlier-resolved condition was insufficient without recurrence of the condition more than six months after the vaccine administration. Based on the testimony at the hearing, however, the Special Master found it conceivable that B.W. may have suffered a psychological response lasting more than six months (and thus satisfying the severity requirement) and requested post-hearing briefs and supporting evidence from each party to that respect. Post-hearing briefs were filed on December 29, 2017, by petitioner and on February 12, 2018, by respondent. Both parties filed expert reports on the psychological issue after that.

Special Master Corcoran issued his opinion dismissing the complaint on January 18, 2019. He concluded that this case was indistinguishable from *Crabbe v. Secretary of Health & Human Services*, No. 10-762V, 2011 WL 4436742 (Fed. Cl. Spec. Mstr. Aug. 26, 2011), in which the Special Master held that neither monitoring ITP through platelet counts nor the possibility of recurrence were residual effects. He further held that, even if continued testing constituted "management," that would not mean that the management was necessary to manage symptoms or sequelae of ITP. Decision at 14.

The Special Master also rejected petitioner's separate argument that B.W. showed evidence of separation anxiety that could be traced to the ITP episode. It is not necessary to discuss that issue in any detail, however, because we grant the petitioner's motion on other grounds.

On February 19, 2019, petitioner filed the present motion for review. Respondent filed a response on March 21, 2019. Oral argument was held on July 11, 2019.

DISCUSSION

I. Standard of Review

On a motion for review, the court can: (1) uphold the special master's finding of fact and conclusions of law and sustain his decision, (2) set aside any of the special master's finding of fact or conclusions of law that are found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" and issue our own findings of fact and conclusions of law, or (3) remand to the special master for further action according to this court's discretion. 42 U.S.C.S. § 300aa-12(e)(2)(A)-(C) (2012).

Findings of fact are reviewed under the arbitrary and capricious standard; legal conclusions are reviewed de novo, and discretionary decisions are reviewed under the abuse of discretion standard. *Munn v. Sec'y of Dep't of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992). Weighing and evaluating factual evidence and determining its probative value are within the Special Master's purview as fact finder. *Broekelschen v. Sec'y of Health & Human Servs.*, 89 Fed. Cl. 336, 343-44 (2009). On review, we do not reweigh, reevaluate or redetermine the value of factual evidence unless the Special Master is found to have been arbitrary and capricious, in which case we may "substitute [our] own findings of fact" if

we determine that the Special Master was arbitrary and capricious in his review. *Id.*; *Munn*, 970 F.2d at 870.

In this case, we have no reason to question the Special Master's thorough analysis of the facts; rather, we reach a different conclusion on an admittedly close question of law.

II. Petitioner's Record Demonstrates That Petitioner Suffered Residual Effects Of The Vaccine-Related Illness More Than Six Months After Receiving The Vaccine

Petitioner argues that the Special Master erred in holding that B.W.'s repeated platelet testing six months after receiving the vaccination and beyond was not a residual effect or complication as required by the statute. Because the platelet tests were necessary given the subsequent manifestation of symptoms, petitioner asserts that this was treatment or management of B.W.'s condition and thus met the statutory requirement.

In doing so, Ms. Wright also challenges the Special Master's reliance on *Crabbe* because, unlike in *Crabbe*, her son's treating physicians ordered subsequent platelet counts in response to his history of ITP and "their desire to ensure that his platelets permanently stabilized so he would not suffer any relapses." Pet'r's Mot. for Review 16. Petitioner cites two other cases as helpful, *H.S. v. Secretary of Health & Human Services*, No. 14-1057V, 2005 WL 1588366 (Fed. Cl. Spec. Mstr. Mar. 13, 2015) and *Faup v. Secretary of Health & Human Services*, No. 12-87V, 2015 WL 443802 (Fed. Cl. Spec. Mstr. Jan. 13, 2015). In those cases, the doctors' concern about the presence of a vaccine-injury, as evidenced by continuing physical restrictions and on-going medication, were found to be residual effects of the injuries, even if the patient was asymptomatic at the time of these continuing effects. Petitioner analogizes this to her case, arguing that, just as relapse-preventing restrictions and medication are residual effects because they manage the "underlying vaccine injury," B.W.'s platelet tests are residual effects because they too manage his underlying vaccine-injury. Pet'r's Mot. for Review 17.

At oral argument, petitioner argued that the court need not narrowly construe the statute using medical definitions because the plain meaning of "residual effects" is clear. Counsel urged the court to define the term broadly to encompass any subsequent monitoring for an earlier vaccine-related injury even if the injury has been resolved.

For its part, respondent agrees with the Special Master that petitioner did not show by a preponderance of evidence that B.W. suffered residual effects of his vaccine-related injury for more than six months. It emphasizes Dr. Bailey's July 8, 2014 notation that B.W.'s ITP was resolved and cites *Crabbe* as persuasive.[6] Respondent argues that only "symptoms that manifest because of the vaccine-related injury" are residual effects necessitating compensation under the Vaccine Act. Resp't's Resp. 8 (emphasis omitted) (citing *Parsley v. Sec'y of Health & Human Servs.*, No. 08-781V, 2011 WL 2463539, at *16 (Fed. Cl. Spec. Mstr. May 27, 2011)).

Further, respondent disputes that the tests B.W. received more than six months after his vaccination were monitoring or treatment of ITP because CBCs are merely diagnostic tests and did not show a recurrence of the injury. The tests were not a residual effect because B.W. was never re-diagnosed with ITP, urges Respondent. To be compensable, the government argues, the residual effects or complications "must manifest as a symptom." Resp't's Resp. 12. The government also flags in the record the notation that the subsequent tests were ordered at Ms. Wright's request, and suggests that they are thus not reflective of any concern of the treating physicians.

The question posed by the respondent is whether what occurs after the six-month period must be a recurrence within the patient of the prior medical condition or of some physical sequela resulting from that condition, as opposed to merely treatment or management done to the patient, even if physical symptoms trigger a concern that there has been a relapse.

There is no question that the testing was triggered by the prior ITP. In that sense, the testing is causally linked to the condition. We understand respondent's concern that, if a condition has fully resolved, prescribing monitoring to occur beyond the six-month period is a very attenuated link to the severity concerns of the Act. For that reason, respondent argues that the "residual effects" requirement should involve something more than mere cause and effect in a general sense. Instead, it prefers the medical definition of "residual effect" relied on in *Parsley*: "refer[s] to something left behind or

[6] Respondent also relies on testimony from Drs. Shaer and Gill for this point.

resulting from an illness, disability, or condition." 2011 WL 2463539 at *61.[7] I.e., a return of the condition or physical sequela.

This definition often precludes claimants who suffer a vaccine related injury from compensation if the injury resolves before the six-month time frame and not does return, even if the patient is tested for possible recurrence later. *See, e.g.*, *Id.* at *16; *Crabbe*, 2011 WL 4436742 at *20. Petitioner did not offer a competing dictionary definition but, at oral argument, suggested that the Act's severity requirement be interpreted based the plain meaning of its terms because it is not ambiguous. Under either approach, we find that petitioner has met the test. *See United States v. Ron Pair Enters.*, 489 U.S. 235, 240-41 (1989) (explaining that a court need not inquire beyond a statute's plain language when the statutory scheme is coherent and consistent).

The Special Master relied on *Crabbe*, calling it "indistinguishable" from the case before us. In *Crabbe*, a child was diagnosed with ITP after receiving the MMR vaccine and underwent platelet counts more than six months after the vaccination, once when he was presented with "redness around his eyes and neck" and the other when he was presented with a runny nose and high fever. Both blood tests showed normal platelet levels; thus, the Special Master concluded that platelet tests were not "residual effects" because they were merely testing for a possible recurrence of ITP. In *Crabbe*, the petitioner did not offer expert witness testimony to the effect that the child's "problems [were] related to the vaccine injury." *Crabbe*, No. 10-762V, 2011 WL 4436742 at *17 (citing *Song v. Sec'y, Health & Human Servs.*, 31 Fed. Cl. 61, 63 (1994)).

Unlike in *Crabbe*, however, the platelet tests B.W. underwent after September 28, 2014 (January 26, 2015, April 13, 2016, and September 14, 2016), were ordered because B.W. presented with bruising and, in one instance, petechiae, both of which are symptoms of ITP. *See* 42 C.F.R. § 100.3 (c)(7). The record is clear that the treating physicians ordered platelet

[7] Both parties refer to this definition of residual effects, and it is the definition relied upon in *Crabbe*. *See* Resp't's Resp. 8; Pet'r's Mot. for Review 15 n.4; *Crabbe*, 2011 WL 4436742 at *20. The Special Master in *Parsley* relied on *Abbott v. Sec'y of Health & Human Servs.*, 27 Fed. Cl. 792 (1993), *rev'd on other grounds*, 19 F.3d 39 (Fed. Cir. 1994) to define residual effect based on how a medical professional would understand the term.

counts because of B.W.'s history of ITP. Both sides' expert witnesses agreed that this response—ordering platelet counts when a patient with a history of ITP is presented with bruising—was within the doctor's reasonable standard of care. The present case, therefore, poses circumstances in between physical sequela of the condition and mere monitoring. We thus conclude that it is, in fact, distinguishable from *Crabbe* because the subsequent testing in this case was directly related to B.W.'s presentation of symptoms of ITP.

The response of B.W.'s doctors to his bruising is analogous to that in *H.S. v. Secretary of Health & Human Services.* In *H.S.*, a patient who fractured his skull after an episode of syncope following a vaccination was compensated under the Vaccine Act because his physician's instruction to restrict physical activity continued more than six-months after he received the vaccine, even though the patient did not exhibit on-going symptoms. 2005 WL 1588366 at *8-9. The Special Master concluded that the activity restriction was a sufficient residual effect to allow for compensation. She found that the patient's doctors "believed that the restriction from activity was medically necessary as part of H.S.'s treatment precisely to ensure that further consequences of the injury would *not* manifest in the future." *Id.* at *8 (emphasis in original). Similarly, because B.W.'s doctors were exercising a reasonable standard of care by testing his platelets in response to the bruising he continued to exhibit more than six months after vaccination, those tests were also causally connected to the vaccine injury, and, we conclude, a residual effect.[8]

Using either the definition supplied by *Parsley* or a more general understanding of the terms, testing for a condition that could return ought to be compensated under the Vaccine Act when that testing is causally connected to the underlying vaccine-injury and triggered by subsequent symptoms of the conditions. The fact that those tests did not reveal the presence of ITP is not controlling. The tests became necessary when later symptoms triggered concern because of the earlier injury; they were not mere monitoring.

[8] Respondent conceded at oral argument that B.W.'s platelet tests were connected to his history of ITP. Dr. Gill, testifying on behalf of respondent before the Special Master, likewise testified that it is unlikely B.W. would have undergone continued platelet testing if it were not for his history with ITP.

Our conclusion is consistent with the purpose of the Vaccine Act, which is to award "vaccine-injured persons quickly, easily, and with certainty and generosity." *Weddel v. Sec'y of Health & Human Servs.*, 100 F.3d 929, 932 (Fed. Cir. 1996) (quoting H.R. Rep. No. 99-908, at 3 (1986)). The act was meant to remedy the problem that "the opportunities for redress and restitution are limited, time consuming, expensive, and often unanswered" "for the relatively few who are injured by vaccines—through no fault of their own." *Cloer v. Sec'y of Health & Human Servs.*, 654 F.3d 1322, 1325 (Fed. Cir. 2011) (quoting H.R. Rep. No. 99-908, at 4 (1986)). By establishing a rule of prima facie proof for Table claims, the Act further "establishes a scheme of recovery designed to work faster and with greater ease than the civil tort system." *Shalala v. Whitecotton*, 514 U.S. 268, 269-70 (1995) (citing H.R. Rep. No. 99-908, at 3-17 (1986)). Given this purpose, we hold that the Act's severity requirement is met when a petitioner has suffered an injury recognized by the Act and, for more than six months after the vaccine was administered, repeatedly undergoes unscheduled medical tests triggered by symptoms directly linked to the asserted vaccine-related injury.

CONCLUSION

Because the record indicates that B.W.'s on-going platelet counts were a result of the ITP he suffered following his MMR vaccine, we conclude that the Special Master erred as a matter of law in holding that there was no residual effect of the vaccine-related injury within the meaning of the Act. We therefore grant petitioner's motion for review and remand the case back to the Special Master for further proceedings consistent with this opinion.

s/Eric G. Bruggink
ERIC G. BRUGGINK
Senior Judge